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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/785,673	02/23/2004	Conceicao Minetti	13564-105004US3	3568
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EXAMINER DEVI, SARVAMANGALA 7 N				
ART UNIT 1645		PAPER NUMBER		
NOTIFICATION DATE 10/20/2008		DELIVERY MODE ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

usptomailnyc@kslaw.com

### Office Action Summary

**Application No.**

10/785,673

**Applicant(s)**

MINETTI ET AL.

**Examiner**

S. Devi, Ph.D.

**Art Unit**

1645

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 July 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 16-21 and 27-40 is/are pending in the application.
- 4a) Of the above claim(s) 27-30 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 16 and 32-40 is/are allowed.
- 6) ☒ Claim(s) 17-21 and 31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SF/08)  
Paper No(s)/Mail Date 07/24/08
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **Continued Examination under 37 C.F.R 1.114**

1) A request for continued examination under 37 C.F.R 1.114, including the fee set forth in 37 C.F.R 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 C.F.R 1.114, and the fee set forth in 37 C.F.R 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 C.F.R 1.114. Applicant's submission filed on 07/24/08 has been entered.

### **Applicant's Amendment**

2) Acknowledgment is made of Applicant's amendment filed 05/14/08 in response to the final Office Action mailed 02/15/08.

### **Status of Claims**

3) Claims 16, 17, 19-21 and 31-40 have been amended via the amendment filed 11/29/07.  
Claims 16-21 and 27-40 are pending.  
Claims 16-21 and 31-40 are under examination.

### **Information Disclosure Statement**

4) Acknowledgment is made of Applicants' information disclosure statement filed 07/24/08. The information referred to therein has been considered and a signed copy is attached to this Office Action.

### **Prior Citation of References**

5) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

### **Objection(s) Withdrawn**

6) The objection to claim 20 made in paragraph 20 of the Office Action mailed 02/15/08 is withdrawn in light of Applicants' amendment to the claim.

### **Rejection(s) Withdrawn**

7) The rejection of claims 32-40 made in paragraph 10 of the Office Action mailed 05/29/07 and maintained in paragraph 13 of the Office Action mailed 02/15/08 under 35 U.S.C. § 101 as

being directed to non-statutory subject matter, is withdrawn in light of Applicants' amendment to the claims.

**8)** The rejection of claim 17 and the dependent claims 18-21 and 31 made in paragraph 11 of the Office Action mailed 05/29/07 and maintained in paragraph 14 of the Office Action mailed 02/15/08 under 35 U.S.C. § 112, first paragraph, as containing new matter, is withdrawn in light of Applicants' amendment to claim 17.

**9)** The rejection of claim 17 made in paragraph 14(e) of the Office Action mailed 05/29/07 and maintained in paragraph 15 of the Office Action mailed 02/15/08 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to claim 17.

**10)** The rejection of claims 18-21 and 31 made in paragraph 14(f) of the Office Action mailed 08/29/07 and maintained in paragraph 16 of the Office Action mailed 02/15/08 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to claim 17.

**11)** The rejection of claims 19-21 made in paragraph 17 of the Office Action mailed 02/15/08 under 35 U.S.C. § 112, first paragraph, as containing new matter, is withdrawn in light of Applicants' amendment to the claims.

**12)** The rejection of claims 32-40 made in paragraph 19(b) of the Office Action mailed 02/15/08 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claims.

### **Rejection(s) Maintained**

**13)** The rejection of claim 20 made in paragraph 19(a) of the Office Action mailed 02/15/08 under 35 U.S.C. § 112, second paragraph, as being indefinite, is maintained for the reasons set forth therein and herein below.

Although Applicants have amended the claim, the previous limitation, 'mammalian and insect cells', continues to be present in the claim. As suggested previously, the replacement of the above-identified limitation with the limitation --mammalian cells and insect cells-- would obviate the rejection.

**14)** The rejection of claim 21 made in paragraph 19(c) of the Office Action mailed 02/15/08 under 35 U.S.C. § 112, second paragraph, as being indefinite, is maintained for the reason set forth therein.

**Rejection(s) under 35 U.S.C. § 112, First Paragraph**

**15)** The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

**Rejection(s) under 35 U.S.C. § 112, First Paragraph (New Matter)**

**16)** Claim 17 and the dependent claims 18-21 and 31 are rejected under 35 U.S.C § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 17, as amended, is drawn to a recombinant nucleic acid molecule comprising 'variants of the nucleic acid sequence of SEQ ID NO: 1, said variants including changes in the nucleic acid sequence of SEQ ID NO: 1 that do not result in a change in the polypeptide encoded by the recombinant nucleic acid molecule'. The amendment requires that the claimed recombinant nucleic acid molecule comprises the recited 'variants' of SEQ ID NO: 1 include any number of unspecified changes, but which changes do *not* result in a change in the polypeptide encoded by the recombinant nucleic acid molecule comprising the variants of SEQ ID NO: 1. Applicants contend that the original specification at page 33, line 30 to page 34, line 4 describes nucleotide mutations that do not result in a change in the translated amino acid product. Applicants state that as is well known in the art, such mutations are the result of the fact that several different three-nucleotide combinations or codons code for the same amino acid. The disclosure from line 30 of page 33 through line 4 of page 34 of the as filed specification is reproduced below:

Additional nucleotide mutations may be made that were not identified in the selection process particularly where the translated amino acid is the same as the identified amino acid predicted based on the sequence of the selected clone. In addition, nucleotide changes may

This part of the specification however does not support a recombinant nucleic acid molecule comprising 'variants' of SEQ ID NO: 1 that include 'changes' in said SEQ ID NO: 1 that do not result in 'a change in the polypeptide encoded' by the claimed recombinant nucleic acid molecule. A recombinant nucleic acid molecule comprising unlimited 'variants' of SEQ ID NO: 1 that include unlimited unspecified changes in said SEQ ID NO: 1 as claimed, wherein the unlimited and unspecified changes do *not* result in a single change in the structure and/or function of the polypeptide encoded by said recombinant nucleic acid molecule lacks descriptive support in the specification as originally filed. Therefore, the above-identified limitations in the claim(s) and the now claimed scope of the claims are considered to be new matter. *In re Rasmussen*, 650 F2d 1212 (CCPA, 1981). New matter includes not only the addition of wholly unsupported subject matter but also, adding specific percentages or compounds after a broader original disclosure, or even omission of a step from a method. See M.P.E.P 608.04 to 608.04(c).

Applicants are respectfully requested to point to the descriptive support in the specification as filed, for the new limitation(s), or alternatively, remove the new matter from the claim(s). Applicants should specifically point out the support for any amendments made to the disclosure. See MPEP 714.02 and 2163.06.

### **Rejection(s) under 35 U.S.C. § 112, Second Paragraph**

**17)** The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his/her invention.

**18)** Claims 17-21 and 31 are rejected under 35 U.S.C § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter, which Applicants regard as the invention.

(a) Claim 17, as amended, is indefinite, confusing, and internally inconsistent in the limitation: 'variants of the nucleic acid sequence of SEQ ID NO: 1, said variants including changes in the nucleic acid sequence of SEQ ID NO: 1 that do not result in a change in the polypeptide encoded by the recombinant nucleic acid molecule'. It is unclear how a recombinant nucleic acid molecule comprising any number of 'variants' of SEQ ID NO: 1 that include any number of unspecified changes in SEQ ID NO: 1 can result in an encoded polypeptide having

*not* a single structural or functional change. Note that the one or more nucleotide substitutions recited in the last half of the claim indicate that the encoded polypeptide would necessarily have at least one amino acid change.

(b) Claim 17 is indefinite in the limitation: 'variants of the nucleic acid sequence of SEQ ID NO: 1', because it is unclear what is encompassed in the limitation 'variants'. What constitutes 'variants', and how much of the SEQ ID NO: 1's original structure has to be retained such that the resulting products can be considered as 'variants' is not clear. The metes and bounds of the structure encompassed in the limitation 'variants' is indeterminate.

(c) Claim 17 is indefinite because of the improper antecedent basis in the limitation: 'the polypeptide'. There is no earlier recitation of a polypeptide in the claim.

(d) Claim 17 is further vague and indefinite in the limitation: 'said nucleic acid sequence' (see line 6), because it is unclear where does the limitation derive its antecedence from. Is this 'said nucleic acid sequence' SEQ ID NO: 1, or variant of SEQ ID NO: 1?

(e) Claims 18-21 and 31, which depend from claim 17, are also rejected as being indefinite because of the indefiniteness identified above in the base claim.

### **Remarks**

**19)** Claims 17-21 and 31 stand rejected. Claims 16 and 32-40 are allowable.

**20)** Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. The Fax number for submission of amendments, responses and/or papers is (571) 273-8300, which receives transmissions 24 hours a day and 7 days a week.

**21)** Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.Mov>. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (in USA or CANADA) or 571-272-1000.

**22)** Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Robert Mondesi, can be reached at (571) 272-0956.

/S. Devi/  
S. Devi, Ph.D.  
Primary Examiner  
AU 1645

October, 2008